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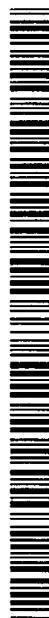
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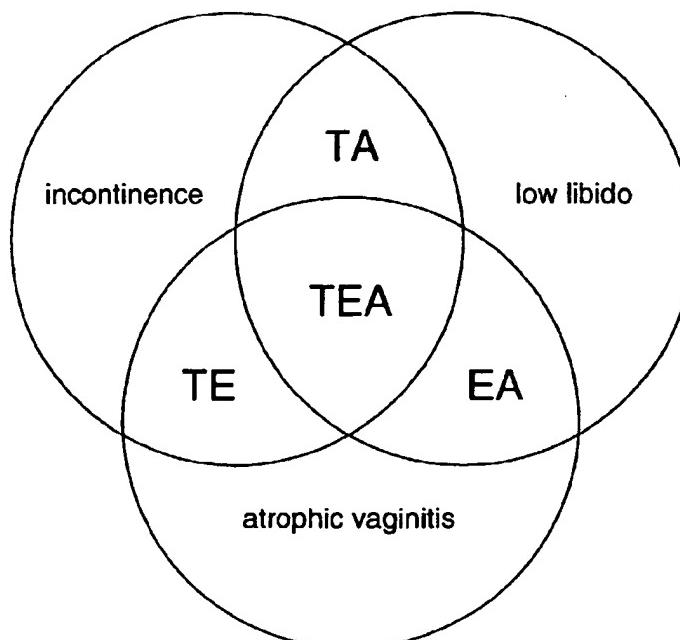
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(54) Title: COMPOSITIONS FOR TREATMENT OF POSTMENOPAUSAL FEMALE SEXUAL DYSFUNCTION



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(57) Abstract: A set of pharmaceutical dosage forms is provided, each comprising at least two therapeutic agents selected from (a) an estrogen, (b) an androgen, and (c) an antimuscarinic, in total and relative dosage amounts that are therapeutically effective in treatment of female sexual dysfunction (FSD) or postmenopausal sexual avoidance (PMSA), said dosage forms being adapted for intravaginal administration. A method of treatment of FSD or PMSA comprises administering intravaginally, in a treatment regimen extending over a period of at least 7 days, dosage forms at least a portion of which comprise two or more therapeutic agents selected from (a) an estrogen, (b) an androgen, and (c) an antimuscarinic, in total and relative dosage amounts that are therapeutically effective in treatment of FSD or PMSA, wherein no more than one dosage form is administered on any day. Also provided is a kit useful in implementing such a treatment regimen.

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— *with amended claims*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AMENDED CLAIMS

[received by the International Bureau on 23 May 2003 (23.05.03)
claims 1-24 substituted by claims 1-17]

WHAT IS CLAIMED IS:

1. A pharmaceutical dosage form comprising an estrogen and an antimuscarinic, in total and relative dosage amounts that are therapeutically effective in treatment of female sexual dysfunction or disorders contributing thereto, said dosage form being adapted for intravaginal administration.
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2. The dosage form of Claim 1 wherein said total and relative dosage amounts are therapeutically effective in treatment of female sexual dysfunction characterized at least by atrophic vaginitis and anxiety arising from urinary incontinence.
3. The dosage form of Claim 1 that is a vaginal dosage form selected from the
10 group consisting of tablets, ovules, pessaries, creams, ointments, gels, foams, sponges and implants.
4. The dosage form of Claim 1 that is a vaginal tablet.
5. The dosage form of Claim 1 wherein the estrogen is a nonsteroidal estrogen selected from the group consisting of broparoestrol, chlorotrianisine, dienestrol,
15 diethylstilbestrol, fosfestrol, hexestrol, methestrol and salts and esters thereof.
6. The dosage form of Claim 1 wherein the estrogen is a steroid estrogen selected from the group consisting of copromon, conjugated estrogenic hormones, equilenin, equilin, estradiol, estriol, estrone, ethynodiol, mestranol, moxestrol, quinestradiol, quinestrol and salts and esters thereof.
- 20 7. The dosage form of Claim 1 wherein the estrogen is estradiol.
8. The dosage form of Claim 1 wherein the antimuscarinic is selected from the group consisting of oxybutynin, tolterodine, the 5-hydroxymethyl metabolite of tolterodine and salts and esters thereof.
9. The dosage form of Claim 1 wherein the antimuscarinic is tolterodine or a
25 pharmaceutically acceptable salt thereof.
10. A pharmaceutical dosage form comprising an estrogen and an antimuscarinic, in total and relative dosage amounts that are therapeutically effective in treatment of postmenopausal sexual avoidance, said dosage form being adapted for intravaginal administration.
- 30 11. The dosage form of Claim 10 that is a vaginal dosage form selected from the

- group consisting of tablets, ovules, pessaries, creams, ointments, gels, foams, sponges and implants.
12. The dosage form of Claim 10 that is a vaginal tablet.
13. The dosage form of Claim 10 wherein the estrogen is a nonsteroidal estrogen selected from the group consisting of broparoestrol, chlorotrianisine, dienestrol, diethylstilbestrol, fosfestrol, hexestrol, methestrol and salts and esters thereof.
14. The dosage form of Claim 10 wherein the estrogen is a steroid estrogen selected from the group consisting of colpormon, conjugated estrogenic hormones, equilenin, equilin, estradiol, estriol, estrone, ethinyl estradiol, mestranol, moxestrol, quinestradiol, quinestrol and salts and esters thereof.
15. The dosage form of Claim 10 wherein the estrogen is estradiol.
16. The dosage form of Claim 10 wherein the antimuscarinic is selected from the group consisting of oxybutynin, tolterodine, the 5-hydroxymethyl metabolite of tolterodine and salts and esters thereof.
- 15 17. The dosage form of Claim 10 wherein the antimuscarinic is tolterodine or a pharmaceutically acceptable salt thereof.